Paper No. 49

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte AIMEE G. POURRAT
and
HENRY POURRAT

Appeal No. 1997-2385
Application No. 08/271,571[1]

ON BRIEF

Before WINTERS, SPIEGEL, and MILLS, Administrative Patent Judges.

SPIEGEL, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 30 through 34, which are all of the claims pending in this application.[2]

[1] Application for patent filed July 7, 1994. According to appellants, this application is continuation of application 08/032,456, filed March 17, 1993, now abandoned, which is a continuation of application 07/736,040, filed July 25, 1991, now abandoned.

[2] In the Office action mailed November 3, 1993 (Paper No. 16), the examiner indicated that the amendment and substitute specification filed March 17, 1993 by appellants (Paper No. 14) had been entered. The examiner also indicated that claims 13 through 15 and 17 through 22 had been cancelled in the Office action mailed November 16, 1994 (Paper No. 29) in accordance with the amendment filed July 7, 1994 (Paper No. 27). These clerical oversights should be corrected upon return of this application to the jurisdiction of the examiner.

Appellants' invention relates to the recovery of therapeutically active ingredients from botanical plants, which ingredients would be lost by the plants due to enzymatic activity in the plants between the time of harvesting and the time of processing (Brief,[3] p. 2). By first rehydrating relatively newly harvested plants to bring their water content close to the initial water content of freshly harvested plants and then subjecting these rehydrated plants to ultrahigh frequency treatment until the plants reach a temperature at least equal to the denaturation temperature of the enzymes in the plants, the enzymatic activity is destroyed without modifying therapeutically active ingredients contained in the plants. Id. p. 3. At least 90% of the therapeutically active ingredients contained in the plants at the time of harvest is recoverable by conventional means. Id. p. 3.

Claim 30 is representative of the claims on appeal.

> 30. A process for stabilizing plants containing enzymes and therapeutic active ingredients that includes the steps of
> providing harvested plants of one variety containing not less than two-thirds of the plants' original water content at the time of harvest, said plants further containing enzymes having a lower denaturation temperature than that of the therapeutic active ingredient,
> determining the denaturation temperature of said enzymes,
> rehydrating the harvested plants at ambient temperature to restor the plants' water content to about 95% of that at the time of harvest,
> exposing the rehydrated plants to ultra high frequency radiation,
> monitoring the temperature of said plants during the radiation step,
> immediately terminating the radiation exposition when said predetermined denaturation temperature of said enzymes has been reached, and

[3] Paper No. 41½, filed January 2, 1996.

recovering at least 90% of the therapeutic active ingredients contained in the plants at the time of harvest.

The references relied upon by the examiner are

Sugisawa et al. (Sugisawa)	4,520,574	Jun. 4, 1985
Palmer	4,681,770	Jul. 21, 1987
Lioutas	4,832,969	May 23, 1989

Grounds of Rejection

Claims 30 through 34 stand rejected under 35 U.S.C. § 112, first paragraph, as being nonenabled by the specification.[4] Claims 30 through 34 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Claims 30 through 34 stand rejected under 35 U.S.C. § 103 as being obvious over Palmer, Sugisawa or Lioutas in view of appellants' admissions on page 1, lines 25-28 of the specification.[5]

We REVERSE all the above grounds of rejection.

1. Rejection of claims 30-34 under § 112, first paragraph, lack of enablement

[4] Although the examiner referred to claim 30 in his objection to the specification under 35 U.S.C. § 112, first paragraph, in the Office action mailed May 2, 1995 (Paper No. 33, p. 2), no claims were correspondingly finally rejected under § 112, first paragraph, for lack of enablement. Therefore, while the record indicates the examiner's apparent intention to reject at least claim 30 for lack of enablement, technically the rejection of claims 30-34 under § 112, first paragraph, in the Answer (Paper No. 42, filed July 10, 1996, p. 6) may be considered a new ground of rejection. However, appellants have argued this rejection in their Reply Brief (Paper No. 44, filed July 29, 1996, pp. 1-2). Therefore, under these circumstances and in view of the length of time this appeal has been pending, we will review the rejection of claims 30-34 under § 112, first paragraph, for lack of enablement at this time.

[5] This is a different statement of rejection than previously made, i.e., the examiner finally rejected claims 30-34 under § 103 as being unpatentable over Palmer or Sugisawa in view of Lioutas and admissions in the specification (emphasis added, Paper No. 33, p. 4).

It is well settled that the examiner bears the initial burden of providing reasons why a supporting disclosure does not enable a claim. In re Marzocchi, 439 F. 2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). It has long been held that "[t]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " Genentech, Inc. v. Novo Nordisk, A/S, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting from In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Further, in In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court stated that

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman [230 USPQ 546, 547 (Bd. Pat. App. Int. 1986)]. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. [Footnote omitted.]

These factors are neither mandatory nor cumulative. Enzo Biochem Inc. v. Calgene Inc., 188 F.2d 1362, 1371, 52 USPQ2d 1129, 1136 (Fed. Cir. 1999).

Here, the examiner argues that the "[d]etermination of the denaturation temperature of the therapeutic active ingredient and the plant enzymes are not enabled by the specification" (Answer, p. 4) because "nowhere in the specification is found how one of ordinary skill would know which enzymes are found in the plant of interest nor how to

determine what their denaturation temperature would be under the unspecified conditions and time period" (Answer, p. 5). Thus,

> [i]t is the examiner's position that to practice the presently claimed invention, one would need to selectively denature most of the majority of the enzymes in a plant, the undesired enzymes, while 90% of the desired enzymes would not be denatured, under identical conditions without prior separation. All of these enzymes would be found in the same plant. [Supplemental answer,[6] p. 2.]

After reviewing the record, we do not find that the examiner has established a prima facie case of lack of enablement.

First, the examiner's conclusory statement that the specification "is not enabling to teach one of skill what the relative denaturation temperatures of the therapeutic active ingredient and undesired enzymes are, nor how to find them" (Answer, p. 4) is unsupported by evidence or a reasoned analysis under Wands.

Second, the specification not only provides generic guidance suggesting temperatures between 70 and 90E C for denaturation temperatures of plant enzymes (see e.g., Background of the Invention) but also provides a number of specific working examples (see e.g., Example 3). The examiner has not provided no reason why this disclosure is insufficient to enable the invention.

Third, to the extent that the examiner appears to equate "desirable plant enzymes" (versus undesirable plant enzymes) to the therapeutic active ingredients of the claims (see

[6] Paper No. 45, mailed August 29, 1996.

Supplemental answer, p. 2), the examiner once again cites no evidence and makes no Wands analysis showing on this record that one of ordinary skill in the art would have had any particular difficulty in carrying out the claimed invention without undue experimentation. Moreover, it is not a function of the claims to specifically exclude possible inoperative embodiments. Atlas Powder Co. v. E.I. Dupont de Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 414 (Fed. Cir. 1984). Of course, if the number of inoperative embodiments becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be nonenabled. However, that has not been shown to be the case here.

In view of the foregoing, we find that the examiner has not established a prima facie case of lack of enablement. Accordingly, we will not sustain this rejection.

2. Rejection of claims 30-34 under § 112, second paragraph, as indefinite

We begin with the proposition that "the definiteness of the language employed [in a claim] must be analyzed -- not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art." In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971) (footnote omitted).

Claim 30 requires that the process provide "harvested plants of one variety." According to the examiner, the use of the phrase "one variety" in claim 30 is indefinite

because it "does not specify which variety" of harvested plant it refers to (Answer, p. 9). However, we see no reason why the skilled artisan would find the phrase "one variety," i.e., a single variety, of harvested plant indefinite when read in light of the specification, as argued by appellants (Brief, para. bridging pp. 11-12).

With respect to the plural and singular use of therapeutic active "ingredient(s)," we agree with appellants that

> plants of a variety may contain a plurality of therapeutic active ingredients and a plurality of enzymes. Some of such enzymes may have a lower denaturation temperature than one therapeutic active ingredient but not another or other therapeutic active ingredient(s) also present in the variety. The use of therapeutic active ingredient in the singular following its use in the plural in the preamble merely signifies this specificity. [Brief, p. 12.]

As to antecedent basis for the phrases "said predetermined" and "the rehydrated plants" in claim 30, antecedent basis for "said predetermined denaturation temperature" is found in the recited step of "determining" said temperature and antecedent basis for "the rehydrated plants" is found in the recited rehydrating step of claim 30, respectively. We remind the examiner that the failure to provide explicit antecedent basis for terms does not always render a claim indefinite, if the scope of claim would be reasonably ascertainable by those skilled in the art. Ex parte Porter, 25 USPQ2d 1144, 1146 (Bd. Pat. App. & Inter. 1992) ("controlled stream of fluid" provided reasonable antecedent basis for "the controlled fluid").

Finally, we find nothing indefinite with the language "that includes the further step" present in claims 31 and 33. The examiner's suggestion of "further including the step of" appears to be no more than alternative grammatical expression.

Accordingly, in view of the foregoing, we will not sustain the rejection of claims 30-34 as indefinite under § 112, second paragraph.

3. Rejection of claims 30-34 under § 103 over Palmer, Sugisawa or Lioutas in view of appellants' admissions on page 1, lines 25-28 of the specification

The initial burden of establishing unpatentability rests on the examiner. In re Oetiker, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). It is also axiomatic that

> Where claimed subject matter has been rejected as obvious in view of a combination of prior art references, a proper analysis under § 103 requires, inter alia, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success. See In re Dow Chemical Co., 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure. Id. See also In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

Here, claim 30 sets forth a number of limitations that are not addressed by the examiner. For example, claim 30 requires (a) plants containing therapeutic active ingredients; (b) that the harvested plants contain no less than two thirds of the plants'

original water content prior to rehydration; (c) rehydrating the harvested plant to 95% of the water content at the time of harvest; and, (d) recovering at least 90% of the therapeutic active ingredient(s) present in the plants at the time of harvest. The examiner has not pointed out, and we do not find, where these limitations are disclosed or suggested in the applied prior art.

Palmer discloses a process for producing fruit products exhibiting improved organoleptic and visual properties (c. 2, ll. 14-17) by forming a wet blend of solids (including hydrated cereal grains), drying and forming the blend into shaped pieces (c. 6, ll. 19-21). Palmer's process may include subjecting the wet blend with the flake grains to a soaking step to hydrate the flakes (c. 6, ll. 23-25). The wet blend is then dehydrated with conventional dehydrating techniques, such as microwave heating (c. 6, ll. 32-37). Palmer states that the invention is applicable to edible plants (c. 3, ll. 10-14).

Sugisawa discloses a process of drying foods under reduced pressure (c. 1, ll. 6-7). Sugisawa includes vegetable plants as a type of food that can be processed (c. 2, l. 29). According to this process, the food is swelled by vaporizing the water under reduced pressure and then dried "while retaining the swelled condition" (c. 2, ll. 59-62). The drying step can be effected by infrared rays or microwaves (c. 3, l. 66 - c. 4, l. 2).

Lioutas discloses "improved methods for preparing dried green vegetables of improved color stability" (c. 3, ll. 55-57). According to Lioutas' method, vegetables are first

blanched in "an aqueous, alkaline blanch fluid for a time sufficient for enzyme inactivation" (c. 3, ll. 59-61) and then "infused with sufficient amounts of water" (c. 3, ll. 63-65). Subsequently, the infused vegetables are dehydrated (c. 4, ll. 1-3). The drying step can be effected via microwave heating (c. 11, ll. 34-36).

Thus, Palmer, Sugisawa and/or Lioutas fail to disclose or suggest claimed limitations (a) through (d) enumerated supra. Moreover, the examiner's conclusion of obviousness has provided no evidence or analysis or why "those of ordinary skill would have a reasonable expectation of success" that the methods of the prior art would result in the recovery of at least 90% of a therapeutic ingredient(s) present in a plant.

Thus, we find that the examiner has failed to establish a prima facie case of obviousness. Accordingly, we do not reach the rebuttal evidence of the Pourrat Declaration (appended to Paper No. 19, filed February 7, 1994) discussed by appellants in their Brief at pages 8-9.

After considering the entire record before us, we will not sustain the examiner's rejection of claims 30-34 under § 103.

CONCLUSION

To summarize, the decision of the examiner (1) to reject claims 30-34 under 35 U.S.C. § 112, first paragraph, for lack of enablement is reversed; (2) to reject claims 30-34 under 35 U.S.C. § 112, second paragraph, as indefinite is reversed; and, (3) to reject claims 30-34 under 35 U.S.C. § 103 as being obvious over Palmer, Sugisawa or Lioutas in view of appellants' admissions on page 1, lines 25-28 of the specification is reversed.

REVERSED

SHERMAN D. WINTERS Administrative Patent Judge	)
CAROL A. SPIEGEL Administrative Patent Judge	) BOARD OF PATENT) APPEALS) AND) INTERFERENCES

DEMETRA J. MILLS)
Administrative Patent Judge)

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APPEAL NO. 1997-2385 - JUDGE SPIEGEL
APPLICATION NO. 08/271,571

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DECISION: **REVERSED**

Prepared By:

DRAFT TYPED: 26 Sep 01

FINAL TYPED: